1-0628b

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

William A. Cook et al.

Patent No. 4,543,954

Issued October 1, 1985

EXERCISE RESPONSIVE CARDIAC PACEMAKER

June 27, 1988

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APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

SOLICITOR JUN 30 1988 U.S. PATENT & TRADEMARK OFFICE

Hon. Commissioner of Patents and Trademarks

Box Patent Ext.

Washington, D.C. 20231

Sir:

Pursuant to the provisions of 35 U.S.C. §156, and in compliance with 37 C.F.R. §§1.710-.785, Purdue Research Foundation, a corporation of the State of Indiana having its principal place of business located in Hovde Hall, Purdue University, West Lafayette, Indiana 47907, and the owner of record of the above-cited patent, by its undersigned agent, hereby makes application for an extension of the patent term of its United States Patent No. 4,543,954, from March 13, 2001 to April 29, 2002, in accordance with the following.

(1) The approved products that are the subject of this application are medical devices subject to regulation under the Federal Food, Drug, and Cosmetic Act and indicated for exercise responsive cardiac pacing, comprising the following units: Sensor® Model Kelvin® 500 Unipolar Pulse Generator and Model K Unipolar Temperature Sensing Lead, together forming a cardiac pacemaker.

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Date of Deposit June 27, 1988
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR§1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.
Joyce Whitaker
Signature of person mailing paper or fee

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(2) The regulatory review of the approved products was conducted by the Center for Devices and Radiological Health of the Food and Drug Administration under Sections 515 and 520 of the Federal Food, Drug, and Cosmetic Act.

(3) By letter dated April 29, 1988, the Office of Device Evaluation of the Center for Devices and Radiological Health granted permission to begin commercial distribution of the approved products.

(4) This Application is being submitted within the sixty-day (60) period permitted for submission of such applications for extension of patent terms pursuant to 35 U.S.C. §156(d)(1), and 37 C.F.R. §1.720(f), the last day of said sixty-day (60) period being June 27, 1988, which is the last day upon which this Application could be timely submitted.

(5) United States Patent No. 4,543,954 for an "Exercise Responsive Cardiac Pacemaker" is the patent for which a term extension is being sought. United States Patent No. 4,543,954 issued on October 1, 1985, in the names of William A. Cook, Neal E. Fearnot, and Leslie A. Geddes with Purdue Research Foundation as Assignee.

(6) A copy of United States Patent No. 4,543,954, including the entire specification (including claims) and drawings, is appended hereto.

(7) Also attached hereto is a copy of the "Terminal Disclaimer to Obviate a Double Patenting Rejection (37 C.F.R. §1.321(b))," which was filed in Patent Application Serial No. 542,590, which matured into United States Patent No. 4,543,954. There are no other disclaimers, certificates of correction, receipts of maintenance fee payments, or re-examination certificates that have issued to date in United States Patent No. 4,534,954.

(8) The claims of United States Patent No. 4,543,954 read on the approved products identified in paragraph (1) above, and following is a showing which lists each applicable claim of said Patent and demonstrates the manner in which each applicable claim of said Patent reads on the approved product.

The Kelvin 500 pulse generator and the Model K lead together form a cardiac pacemaker including means for variably controlling the stimulation rate of the heart according to the level of muscular exertion in the body, according to at least claims 1 and 2 of United States Patent No. 4,543,954. Following is a showing which demonstrates the manner in which those claims read on the approved products:

(a) Claim 1 reads on the Kelvin 500 pulse generator and the Model K unipolar temperature sensing lead as follows:

A sensor means for sensing a body temperature is provided in the form of a thermistor assembly which is part of the Model K lead.

A stimulus means for applying an electrical stimulus to a heart is provided in the form of a pacing electrode which is also part of the Model K lead.

The Kelvin 500 pulse generator contains a microprocessor circuit with an input connected to the thermistor in the Model K lead for processing of temperature information obtained via the thermistor. The microprocessor circuit is programmed to function as a control circuit means for calculating dT/dt of said sensed body temperature, said control circuit means including means for generating a rate control signal according to a predetermined algorithm relating heart rate to dT/dt.

The Kelvin 500 pulse generator supplies stimulation pulses to the electrode in the Model K lead at a rate which varies according to the rate control signal. The portion of the pulse generator which performs this function is a cardiac pacemaker connected to said control circuit means and said stimulus means and responsive to said rate control signal to variably control the stimulation rate of the heart.

(b) Claim 2 reads on the Kelvin 500 pulse generator and the Model K unipolar temperature sensing lead as follows:

The limitations incorporated into claim 2 by reference to claim 1 are satisfied by the Kelvin 500 pulse generator and the Model K lead as indicated above.

The algorithm implemented by the microprocessor circuit in the Kelvin 500 pulse generator includes hysteresis in the function relating heart rate to dT/dt, whereby the rate control signal generating means in the microprocessor circuit is operative to generate a rate control signal according to a predetermined algorithm relating heart rate to dT/dt and a previous heart rate.

(9) The relevant dates and information pertinent to 35 U.S.C. §156(g), which are being provided in order to enable the Secretary of Health and Human Services to determine the applicable "regulatory review period," together with a brief description of the activities undertaken during the applicable "regulatory review period" with respect to the approved product, and the significant dates applicable to such activities, follow:

- IDE No. G860081 Submission 5/6/86
- FDA Release of IDE No. G860081 To Start Clinicals 6/5/86

  Approval was granted for 10 core investigators and 35 implants. Pacemakers were monitored and reported under Protocol A.

- Phase I Completion 12/12/86

  Submission to the FDA of data obtained during Phase I and the results of the core investigators meeting held on 11/16/86.
  Request for expansion to Phase II.

- FDA Release for Phase II 1/9/87

  Program expanded to 25 investigators and 100 implants; pacemaker implants were to be followed in accordance to Protocol B. However, additional data was requested.

- Nonconditional Expansion Granted 3/10/87
- PMA No. P870054 Submitted to FDA 9/4/87
- PMA Updates Submitted to FDA 2/17/88
- FDA Panel Meeting 3/11/88
- FDA Release for Commercial Use 4/29/88

(10) In the opinion of Purdue Research Foundation, United States Patent No. 4,543,954 is eligible for an extension of its term as herein requested, and a statement as to the length of the term extension requested, including how the length of the extension was determined, follows:

An extension of the term of Patent No. 4,543,954 of one (1) year and forty-seven (47) days from March 13, 2001 (the original expiration date), to and including April 29, 2002 (the date fourteen (14) years from PMA approval), is being requested hereby.

Pursuant to 35 U.S.C. §156(c), the term of a patent eligible for extension under §156(a) shall be extended by the time equal to the "regulatory review period" (as defined in §156(g)) for the approved products that occurred after the patent issued. Section 156(c) sets forth four (4) exceptions: (1) the eligible period is reduced by any period during which applicant did not act with due diligence (there is no such period pertinent herein); (2) after deductions, if any, under (1), the remaining period calculated under §156(g)(3)(B)(i) (for approved products that are medical devices) is reduced by one-half (1/2); (3) the sum total of the remaining original term of the patent after products approval and the "regulatory review period" (as defined in §156(g)) may not exceed fourteen (14) years; and (4) only one (1) patent may be extended for the same regulatory review period.

The applicable "regulatory review period" herein is calculated under §156(g)(3)(A) and (B), by taking one-half of the period calculated under §156(g)(3)(B)(i) and adding thereto

the period calculated under §156(g)(3)(B)(ii), as follows (see paragraphs (9)-(10), supra):

The date clinical investigations on humans involving the device was begun	6/5/86
The date an application was initially submitted with respect to the device under section 515	9/4/87
Intervening period (i)[§156(g)(3)(B)(i)]	465 days
One-half (1/2) of Intervening period (i)	228 days
The date an application was initially submitted with respect to the device under section 515	9/4/87
The date such application was approved	4/29/88
Intervening period (ii)[§156(g)(3)(B)(ii)]	238 days

The maximum "regulatory review period" to which Purdue Research Foundation is entitled under §156(c) is believed to be the sum of one-half (1/2) of intervening period (i) plus the full intervening period (ii), or 228 days + 238 days = 466 days. However, pursuant to the limiting provisions of §156(c)(3), Purdue Research Foundation believes itself to be entitled to only 412 days of the maximum 466 days from the original expiration date of March 13, 2001, which will extend the term of the '954 Patent to April 29, 2002, a date 14 years from the April 29, 1988, date of the FDA approval of the approved products under the provisions of law under which the subject regulatory review occurred.

(11) Purdue Research Foundation acknowledges its duty to disclose to the Commissioner of Patents and Trademarks and to the Secretary of Health and Human Services any information which is material to any determination that is to be made relative to the instant application for extension of patent term.

(12) The prescribed fee of $550.00 for receiving and acting upon the instant application for extension of patent term, and the declaration of undersigned authorized agent of the Purdue Research Foundation supporting the instant application for extension, are appended hereto.

(13) The name, address, and telephone number of the person to whom inquiries and corrspondence relating to this application are to be directed is: Clifford W. Browning, Woodard, Emhardt, Naughton, Moriarty & McNett, One Indiana Square, Suite 2000, Indianapolis, Indiana 46204, (317) 634-3456.

Respectfully submitted,
PURDUE RESEARCH FOUNDATION

By _____

C. David Emhardt
Reg. No. 18,483
Clifford W. Browning
Reg. No. 32,201
Woodard, Emhardt, Naughton
Moriarty & McNett
One Indiana Square, Suite 2000
Indianapolis, Indiana 46204
(317) 634-3456

Its Attorney-Agents

2-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	
William A. Cook, et al	Before the Examiner
Serial No. 542,590	M. Shein
Filed October 17, 1983	Group Art Unit 335
EXERCISE RESPONSIVE CARDIAC PACEMAKER	March 25, 1985

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION (37 CFR §1.321(b))

I, William F. Bahret, residing at One Indiana Square, Suite 2600, Indianapolis, Indiana 46204, represent that I am a representative authorized to sign on behalf of the assignee identified below owning all of the interest in this application.

The assignee is Purdue Research Foundation, Hovde Hall, Purdue University, West Lafayette, Indiana 47907. The assignment was recorded on November 30, 1983, Reel No. 4194, Frame Nos. 509-511. The disclaimant is an attorney authorized to sign on behalf of assignee.

I hereby disclaim the terminal part of any patent granted on the above-identified application which would expire beyond the expiration of United States Patent No. 4,436,092 and hereby agree that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to United States Patent No. 4,436,092, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors or assigns.

Enclosed with this paper is the $50.00 fee set forth in 37 CFR §1.20 (d).

William Dahst

Signature of disclaimant

1-06-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:	)	
	)	
William A. Cook et al.	)	
	)	
Patent No. 4,543,954	)	
	)	
Issued October 1, 1985	)	June 27, 1988
	)	
EXERCISE RESPONSIVE CARDIAC PACEMAKER	)	

DECLARATION IN SUPPORT OF APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

Hon. Commissioner of Patents and Trademarks

Box Patent Ext.

Washington, D.C. 20231

Sir:

I, Clifford W. Browning, Esq., Reg. No. 32,201, hereby declare that I am an authorized agent for Purdue Research Foundation, who has general authority from Purdue Research Foundation to act on its behalf in patent matters; that I have reviewed and understand the contents of the Application for Extension of Patent Term Under 35 U.S.C. §156 being filed herewith; that I believe U.S. Patent No. 4,543,594, is subject to extension pursuant 35 U.S.C. §156 and 37 C.F.R. §1.710; that I believe an extension of the term of the length claimed in the Application being submitted herewith is fully justified under 35 U.S.C. §156 and 37 C.F.R. §§1.710-.785; and that I believe U.S. Patent No. 4,543,594 meets the conditions for extension of its term as set forth in 37 C.F.R. §1.720.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR§1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Joyce Whitaker
Signature of person mailing paper or fee

statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent term extension issuing thereon.

June 27, 1988
Date

Signature